MANAGEMENT REVIEW FOR LABORATORIES

PURPOSE

This document gives laboratories guidance on how to establish and implement a program for management reviews.

AUTHORSHIP

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FURTHER INFORMATION

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1. INTRODUCTION

1.1 It is stated in ISO/IEC 17025: 1999 General Requirements for the Competence of Testing and Calibration Laboratories that a laboratory shall establish, implement and maintain a quality system appropriate to the scope of its activities including the type, range and volume of testing and/or calibration activities it undertakes.

1.2 ISO/IEC 17025 requires that the executive management of the laboratory shall periodically conduct a review of the laboratory's quality system and testing and/or calibration activities to ensure their continuing suitability and effectiveness and to introduce any necessary changes or improvements.

1.3 This publication has been prepared to give laboratories guidance on how to establish a program for management reviews. It is assumed that the laboratories have implemented a quality system that meets the requirements of ISO/IEC 17025.

1.4 The guidelines given in this publication are of a general nature. The actual accomplishment of a management review depends on the size, scope and organisational structure of the laboratory and, for a smaller laboratory, many of the items described in this publication can be carried out in a simplified manner.

2 TERMINOLOGY

2.1 **Quality system** Organizational structure, procedures, processes and resources needed to implement quality management (ISO 8402).

2.2 **Quality management** That aspect of the overall management function that determines and implements the quality policy. (ISO 8402).

2.3 **Management review** A formal evaluation by top management of the status and adequacy of the quality system in relation to quality policy and objectives (ISO 8402).

2.4 **Quality manager** The staff member (by whatever title) who has responsibility for the laboratory's quality system and its implementation and who, in this capacity, reports directly to top management.

3 OBJECTIVES OF MANAGEMENT REVIEWS

3.1 The senior management of the laboratory should periodically conduct a review of the laboratory's quality system and testing and/or calibration activities to ensure their continuing suitability and effectiveness and to introduce any necessary changes or improvements.

3.2 Management review should be planned to establish what changes, if any, are necessary to ensure that the quality arrangements for the laboratory continue to meet the laboratory's needs. The review should also ensure that the quality system of the laboratory continues to conform to the requirements of ISO/IEC 17025.

3.3 The management review should also take note of changes that have taken place or need to take place in the organisation, facilities, equipment, procedures, and/or activities of the laboratory.

3.4 The need for changes to the system may also arise as a result of findings from internal or external quality audits, inter-laboratory comparisons or proficiency tests, surveillance visits or assessments by an accreditation body, or complaints from customers.

3.5 The quality policy and goals should be reviewed and revised if necessary. Quality objectives and action plans for the coming year should be set.

4 ORGANISATION OF MANAGEMENT REVIEWS

4.1 The senior management of the laboratory should be responsible for conducting reviews of the quality system.

4.2 Those members of senior management having overall responsibility for the design and implementation of the laboratory's quality system, for the technical operations of the laboratory and for taking decisions resulting from the findings of internal audits and external assessments, should be involved in management reviews.

4.3 The quality manager should be responsible for ensuring that all reviews are conducted in a systematic manner according to an established procedure, and that the results of the management review are recorded.

4.4 The quality manager and operational managers should be responsible for ensuring that actions identified during the management review are implemented within the agreed time.

5 PLANNING OF MANAGEMENT REVIEWS

5.1 Management reviews should be carried out at least once a year. The review should be programmed and the meeting should be attended by the the executive manager, senior operational management, the quality manager and the person under whose authority the quality manual has been issued. It is essential that the head of the laboratory, technical management, the quality manager and any section heads are present.

It is recognised that, in a small laboratory, one person may be fulfilling more than one of the above functions. Good management reviews can occur even in single person laboratories.

6 IMPLEMENTATION OF MANAGEMENT REVIEWS

6.1 The management review should be conducted in a systematic manner using a formal agenda.

6.2 Review should include at least the following items:

(a) matters arising from the previous management review;
(b) quality policy and medium and long term goals;

(c) suitability of quality and operational procedures, including the need for amendment of the quality system (including the quality manual);

(d) reports from managerial and supervisory personnel;

(e) results of internal audits carried out since the last management review, and follow-up actions

(f) analysis of corrective actions and preventive actions;

(g) reports on surveillance visits and assessments carried out by an accreditation body, and follow-up actions of the laboratory;

(h) reports on audits by customers or other approval bodies and follow-up actions;

(i) trends analysis of results of the laboratory's participation in proficiency testing or inter-laboratory comparison schemes, and the need for such participation in other areas of calibration and/or testing;

(j) trends analysis of results of in-house quality control checks;

(k) adequacy of current human and equipment resources

(l) future plans and estimates for new work, additional staff, new equipment, changed methods etc;

(m) training requirements for new staff and for updating of existing staff. Trends analysis of complaints and other feedback received from customers.

6.3 Results of the management should feed into the laboratory planning system and should include:

(a) revision of the quality policy and medium and long term goals;

(b) a planned program for preventive action, including the setting of objectives for the coming year;

(c) formal action plans including time lines for the implementation of changes decided (objectives) for the quality system and for the operations of the laboratory.

6.4 It should be the responsibility of management to ensure that all actions arising from the review are carried out as required and within appropriate and agreed times. Actions and their effectiveness should be monitored at regular management meetings.

7 RECORDS OF MANAGEMENT REVIEWS

7.1 All management reviews should be documented. The documentation may be in the form of minutes of the review meetings together with clear indications as to the actions to be taken, by whom and in what time limit.

7.2 It should be the quality manager's responsibility to ensure that all actions arising from reviews are recorded.

7.3 The records should be readily accessible and retained for an agreed period of time.

8 REFERENCES

EA-4/04: 1996, Internal quality audits and management review for laboratories

ISO/IEC 17025:1999, General requirements for the competence of testing and calibration laboratories

ISO 8402: 1994, Quality Management and Quality Assurance -Vocabulary

ISO 9004-1: 1994, Quality management and quality system elements - Guidelines